

10/21/76

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE REGIONAL ADMINISTRATOR

In the Matter of

Alden-Leeds, Inc.

Respondent

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I.F. & R. Docket No. II-110C
II-111C

INITIAL DECISION

Preliminary Statement

This is a proceeding under Sec. 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136 1(a)), 1973 Supp., for the assessment of a civil penalty for violation of the Act.

On November 28, 1975, the Director of the Environmental Programs Division, United States Environmental Protection Agency, Region II (Complainant), issued two Complaints together with Notices of Opportunity for Hearing, charging Alden-Leeds, Inc. (Respondent) with violations of the Act. An extension of time to February 1, 1976 was granted for the filing of an answer and said answer was duly filed by letter dated January 27, 1976.

The Complaint in Docket No. 110C charged Respondent with violation of Sec. 12(a)(1)(E), 7 U.S.C. §136j(a)(1)(E), by holding for sale on or about November 14, 1974, in South Kearney, New Jersey,

pesticides labeled Nu-Clo Stabilized Tablets, Bleach Ezz Chlorine Tablets and Leeds-All Granular Cyanuric Chlorine, which pesticides were not in compliance with the provisions of FIFRA in that:

- 1) With respect to NU-CLO STABILIZED CHLORINE TABLETS (Sample No. 118435):
 - a. Said product, a pesticide as that term is defined in Section 2(u) of FIFRA, as amended, was misbranded in that the label failed to bear a caution or warning statement which is necessary and, if complied with, adequate to protect health and the environment. (FIFRA, as amended, Section 12(a)(1)(E); Section 2(q)(1)(G).) Specifically said product label failed to bear the precautionary legend: "Do not get in eyes, on skin, or on clothing".
 - b. Said product was misbranded in that the label did not bear on the front panel the signal word "DANGER". (FIFRA, as amended, Section 12(a)(1)(E); Section 2(q)(1)(G).) Specifically said product bore the word "Caution" on the front panel.
- 2) With respect to BLEACH EEZ CHLORINE TABLETS (Sample No. 118436):
 - a. Said product, a pesticide as that term is defined in Section 2(u) of FIFRA, as amended, was misbranded in that the label stated in part: "Trichloro-s-triazinetrione 30%," whereas the product was found to contain significantly more than 30% trichloro-s-triazinetrione. (FIFRA, as amended, Section 12(a)(1)(E); Section 2(a)(1)(A).) Specifically, said product was found to contain approximately 64% trichloro-s-triazinetrione, or approximately 114% over label claims.
 - b. Said product was adulterated in that its strength or purity fell below the professed standard or quality under which it was sold. (FIFRA, as amended, Section 12(a)(1)(E); Section 2(c)(1).)

- 3) With respect to LEEDS-ALL GRANULAR CYANURIC CHLORINE (Sample No. 118437):
 - a. Said product, a pesticide as that term is defined in Section 2(u) of FIFRA, as amended, was misbranded in that the label failed to bear warning or caution statements which are necessary, and if complied with, adequate to protect health and the environment. (FIFRA, as amended, Section 12(a)(1)(E); Section 2(q)(1)(G). Specifically, said product failed to bear the statements: "May cause eye damage and will cause burns on broken skin. Wash thoroughly after using."
 - b. Said product was misbranded in that the precautionary labeling on the front panel was not prominently placed thereon with such conspicuousness as to render it likely to be read under customary conditions of purchase. (FIFRA, as amended, Section 12(a)(1)(E); Section 2(q)(1)(E).) Specifically said product bore the signal word "Warning" and precautionary statement: "Keep Out of Reach of Children" in less than 10 and 14 point type size, respectively.

The Complaint in Docket No. 111C charged Respondent with violation of Section 12(a)(1)(E), 7 U.S.C. §136 1(a)(1)(E), by holding for sale on or about November 14, 1974, in South Kearney, New Jersey, pesticides labeled Nu-Clo Concentrated Swimming Pool Algaecide and Nu-Clo Stabilized Granular Chlorine, which pesticides were not in compliance with the provisions of FIFRA in that:

- 1) With respect to NU-CLO CONCENTRATED SWIMMING POOL ALGAE-CIDE (Sample No. 118440):
 - a. Said product was misbranded in that the label stated in part "n-Alkyl Dimethyl Benzyl ammonium chlorides 8.4%" and "Methyl Benzyl ammonium chlorides 1.6%," whereas said product was found to contain less than the above specified amounts of ammonium chlorides. (FIFRA, as amended; Section 12(a)(1)(E); Section 2(q)(1)(A).)

- b. Said product was adulterated in that its strength or purity fell below the professed standard of quality under which it was sold. (FIFRA, as amended, Section 12(a)(1)(E); Section 2(c)(1).) Specifically said product was found to be approximately 15% deficient in total chlorides as calculated from label claims.
- 2) With respect to NU-CLO GRANULAR STABILIZED CHLORINE (Sample No. 118441):
- a. Said product was misbranded in that the label stated in part; "Sodium dichloro-s-triazinetriene 95%," whereas said product was found to contain less than 95% sodium dichloro-s-triazinetriene. (FIFRA, as amended, Section 12(a)(1)(E); Section 2(q)(1)(A).)
- b. Said product was adulterated in that its strength or purity fell below the professed standard or quality under which it was sold. (FIFRA, as amended, Section 12(a)(1)(E); Section 2(c)(1).) Specifically said product was found to be approximately 9% deficient in sodium dichloro-s-triazinetriene, the only active ingredient.

Civil Penalties have been proposed by Complainant in accordance with the Civil Penalty Assessment Schedule (39 FR 27713) which permits an assessment in each matter broken down as follows:

Docket No. 110C	-	\$ 8,400.00
Docket No. 111C	-	<u>1,800.00</u>
Total		\$10,200.00*

* Sample No. 118440	-	\$1,800.00
Sample No. 118441	-	--
Sample No. 118435	-	2,800.00
Sample No. 118436	-	2,800.00
Sample No. 118437	-	<u>2,800.00</u>
		\$10,200.00

It should be noted that neither the ALJ nor the Regional Administrator is bound by the amount of proposed penalty in the Complaint. See 40 CFR 168.46(b) and 168.60(b)(3).

The Respondent, through its Vice President, filed an Answer which admits that all technical violations alleged did exist. And further, the parties stipulated, EPAX 12, to all other facts relevant to this proceeding, such as the official visit by the Consumer Safety Inspector, the obtaining of the samples, the chain of custody of the samples, the labels in question, the fact that Samples 118440 and 118441 were deficient in the active ingredients, and that Sample 118436 contained 64% of the active ingredient whereas the label claimed only 30%, and to the fact that the product labels did not contain the required precautionary statements.

The question then to be decided here relates solely to the assessment of a civil penalty.

Respondent does assert in its Answer that there are mitigating circumstances as follows:

1. The product labels contained statements which, while maybe not the exact wording required, were in substance equal to those which were required by the Act.
2. Even though an overformulation may have occurred in one sample, the product was in fact a superior product for the claims made and would provide a more effective rate of performance without any adverse reaction or side effects to the public.

3. Even though two samples were deficient in active ingredient, they would still perform as intended.

The proceedings were conducted pursuant to the applicable Rules of Practice, 40 CFR 168.01 et seq. At my request, the parties, pursuant to Sec. 168.36(e) of the Rules, corresponded with me for the purpose of accomplishing some of the purposes of a prehearing conference (see Sec. 168.36(a) of the Rules).

A prehearing conference and a hearing were held in Newark, New Jersey on August 12, 1976. The Complainant was represented by Susan C. Levine, Esquire, of the legal staff of EPA, Region II, and the Respondent was represented by Jerry M. Kaplan, Vice President, Alden-Leeds, Inc.

The parties have filed briefs and reply briefs in support of proposed findings of facts, conclusions of law and order which I have carefully considered.

Findings of Fact

1. The Respondent is a corporation with its place of business located at 55 Jacobus Avenue, South Kearney, New Jersey. Its gross sales are approximately \$3,088,703.00 annually.

2. On or about November 14, 1974, the Respondent held for sale a quantity of the following named pesticides at its establishment in South Kearney, New Jersey:

NU-CLO STABILIZED CHLORINE TABLETS

BLEACH EEZ CHLORINE TABLETS

LEEDS-ALL GRANULAR CYANURIC CHLORINE

NU-CLO CONCENTRATED SWIMMING POOL ALGAECIDE

NU-CLO GRANULAR STABILIZED CHLORINE

3. Samples of the products were collected in accordance with legal procedures by an authorized employee of the United States Environmental Protection Agency on November 14, 1974.

4. All of the products were registered as required by Sec. 4 of the FIFRA, 7 U.S.C. 136(b), at the time they were held for sale.

5. The label on the NU-CLO STABILIZED CHLORINE TABLETS did not set forth the required caution or warning statement "Do not get in eyes, on skin, or on clothing," and did not bear on the front panel the signal word "DANGER."

6. The label on the BLEACH EEZ CHLORINE TABLETS product claimed an active ingredient content of 30% trichloro-s-triazinetriene, whereas the product contained approximately 64% trichloro-s-triazinetriene. The product, therefore, was not of the strength or purity relative to the professed standard or quality under which it was sold.

7. The label on the LEEDS-ALL GRANULAR CYANURIC CHLORINE did not set forth the required caution or warning statements "May cause eye damage and will cause burns on broken skin. Wash thoroughly after using."

8. The pesticide referred to in Finding 7 bore the signal word "Warning" and precautionary statement "Keep Out of Reach of Children" in less than the 10- and 14-point type-size required.

9. The label on the NU-CLO CONCENTRATED SWIMMING POOL ALGAE-CIDE product set forth an active ingredient content of 8.4% n-alkyl dimethyl benzyl ammonium chlorides and 1.6% methyl benzyl ammonium chlorides, whereas the product was found to be approximately 15% deficient in total chlorides as calculated from label claims. Said product was, therefore, adulterated in that its strength fell below the professed standard of quality under which it was sold.

10. The label on the NU-CLO GRANULAR STABILIZED CHLORINE product set forth an active content of 95% sodium dichloro-s-triazinetriene, whereas the product was found to be approximately 9% deficient in sodium dichloro-s-triazinetriene. Said product was, therefore, adulterated in that its strength fell below the professed standard of quality under which it was sold.

11. Respondent is a Category V concern with gross sales exceeding three million dollars annually.

12. For the above mentioned violations, the Respondent is subject to a civil penalty under Sec. 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, 7 U.S.C. 136 1(a).

13. Taking into consideration the size of Respondent's business, the effect on Respondent's ability to continue in business, and the gravity of the violations, it is determined that a penalty of \$10,200 is appropriate.

Discussion and Conclusions

Since the allegations and facts in this matter are undisputed, the case is reduced to a determination as to the amount of the civil penalty to be assessed.

In determining the appropriateness of the penalty, the statute and regulations require that the following factors be considered: size of Respondent's business; effect on Respondent's ability to continue in business; and gravity of the violation. In evaluating the gravity of the violation the regulations require that the following be considered: history of Respondent's compliance with the Act; and good faith or lack thereof.

The Respondent's gross sales for the fiscal year ended July 31, 1975 were approximately \$3,000,000. As to size of company, it falls into category V (annual gross sales exceeding a million dollars) as set forth in the Guidelines for the Assessment of Civil Penalties under FIFRA. (39 FR 27711, July 31, 1974.)

The Respondent does not argue that its annual gross sales are not substantial (one million dollars or more) or that the imposition of a penalty in the proposed amount will effect its ability to continue in business. The Respondent argues, however, that the violations were minor and that no penalty should be imposed.

It has been held in other cases under Sec. 14(a) that "gravity of the violation" should be considered from two aspects--~~gravity of~~ harm and gravity of misconduct.

As to gravity of harm there should be considered the actual or potential harm or damage, including severity, that resulted or could result from the particular violation. . . .^{1/}

As to gravity of harm, Mr. Carlos Rodriguez, an expert toxicologist employed by Complainant, testified that as a part of his duties he performs analyses and reviews toxicological data submitted by manufacturers. Based on this review and analysis, he makes recommendations for use of precautionary labeling.

With respect to the products Nu-Clo Stabilized Chlorine Tablets, Bleach Ezz Chlorine Tablets, and Leeds All Granular Cyanuric Chlorine which contain the active ingredient trichloro-s-triazetrione, Mr. Rodriguez testified that this ingredient is capable of causing cornea opacity and eschar formation and edema when it comes in contact with the eyes or skin respectively. TR p. 20. And that an over-formulation may upgrade the irritation potential to the eye mucosa and mucous membranes. TR p. 28.

Based on his experience as a toxicologist and upon eye and skin irritation studies done by Complainant in 1971 and 1972 on the chemical trichloro-s-triazetrione, Mr. Rodriguez testified that the deficient

^{1/} Quoted from Initial Decision of ALJ In re Amvac Chemical Corporation, published in Notices of Judgment under FIFRA No. 1499, issue of June, 1975.

precautionary labeling for the Nu-Clo Stabilized Chlorine Tablets and Leeds All Granular Cyanuric Chlorine products was of major significance, TR p. 31, due to the fact that the chemical involved was a highly toxic substance.

The deficiencies in active ingredient in Nu-Clo Concentrated Swimming Pool Algaecide and Nu-Clo Granular Stabilized Chlorine are admitted by Respondent in Stipulation EPA Exhibit 12. Since Respondent admits in its testimony that the algaecide deficiency involved a "quality control problem", TR p. 57, we must assume that the deficiency admitted in the Granular Chlorine was due to the same problem, as was the overformulation involved with the Bleach Ezz product. TR p. 53. Respondent had an obligation to assure that products marketed by it met the requirements of the Act and failed to do so. Southern Mill Creek Products, Inc., Notices of Judgment under FIFRA No. 1479, issue of June 1975. Thus the measure of protection intended to be accorded directly through the prevention of injury, rather than having to resort to imposition of sanctions for violations after damage or injury has been done was not available here. H.Rep. No. 813, 80th Cong., 1st Sess. 1947, pp. 2-3.

With regard to gravity of misconduct, Amvac Chemical Corporation, *supra*, stated:

As to gravity of misconduct, matters which may be properly considered include such elements as intention and attitude of respondent; knowledge of statutory and regulatory requirements; whether there was negligence and if so the degree thereof; position and degree of responsibility of those who performed the offending acts; mitigation and aggravating circumstances; history of compliance with the Act; and good faith or lack thereof.

The intention and attitude of Respondent during this proceeding as indicated by the testimony of Mr. Kaplan, its Vice President, as to future compliance by the institution of quality control programs, and further evidenced by the introduction by Respondent into evidence of corrected labels comes a bit too late based upon other factors which came to light during the proceeding.

Respondent was aware of its statutory and regulatory responsibilities which is evidenced by the fact that all of its products which required registration were so registered.

In addition, Respondent was charged with two misbranding violations in January of 1975 and by consent agreement paid a civil penalty of \$300.00.

With regard to both Nu-Clo Stabilized Chlorine Tablets and Leeds All Granular Cyanuric Chlorine, the EPA Registration Division requested changes in the approved labeling for both these products based on the results of eye and skin irritation studies. (See Complainant's exhibits 5 and 8 in evidence, letters of March 24, 1972 and February 22, 1972.) Both letters required Respondent to submit five copies of the corrected labeling. In addition, the February 22, 1972 letter mentions that Respondent did not comply with the requirements of the Registration Division's letter of March 24, 1971 with regard to the Leeds-All product and specifically states that "these requirements must be met to support continued registration of this product." In particular, note the clarification of the front panel precautionary labeling type-size and prominence requirements.

The changes referred to above were requested in 1972. As of 1974, the date of the violations, these changes were still not made. In fact, Respondent only recently changed the labels to conform to EPA requirements (TR p. 66, see Respondent's exhibits 3 and 4).

There was a lapse of approximately three years from the time the changes were requested until the labels were updated. Mr. Kaplan of Alden-Leeds testified that "there was a lag, no question about it. It should have been done at a much better pace than it was. . . ." (TR p. 66.) Yet, certain changes were made in the labeling of the product Nu-Clo Stabilized Chlorine Tablets during this time frame. In a December 3, 1971 letter, Respondent requested that an additional precautionary statement be included in the labeling for the Nu-Clo product. (See Complainant's exhibit 11 in evidence.) Without waiting for EPA approval, Respondent added the additional warning to the label. Mr. Kaplan testified that "this change was started as my letter went out, the change was already being instituted because we did not anticipate any problem with EPA on that, and it may have been printed already. . . that was in the works prior to approval by EPA. I did not know how long it would take EPA, and we felt it was definitely something that should have been put on there . . . at that time I agree with you, it should have been updated. The other label should definitely have been updated to the requirements as the EPA had requested. Why they were not done, I don't know." (TR p. 69). Mr. Kaplan testified that Respondent prints its own labels in its own printing shop.

Mr. Kaplan stated that in his opinion even though the exact precautionary words and statements did not in all instances appear on the labels the statements used were not so different as to reduce their effectiveness upon the user of the products. And that it was based on this opinion, in addition to the fact that he had some recollection of being advised by Complainant that Respondent could use up its stock of labels, that immediate label changes were not accomplished. This latter point could not be substantated however, and, in fact, was refuted by Complainant by reference to its letters of March 24, 1972 and February 22, 1972. EPA Exhibits 5 and 6.

Respondent cannot arbitrarily decide to use up its existing stocks of labels before updating them nor can it be allowed to determine what adequately protects the public. Respondent's failure to include the proper warning and precautionary statements on its labels was in direct contravention of Complainant's notification and resulted in misbranding. These violations in addition to a lack of a quality control program constitute negligence and demonstrated a disregard for the requirements of the Act.

It is difficult, based upon the record of this proceeding, to find even a small degree of good faith effort on the part of Respondent to strictly comply with the requirements of the Act and Regulations.

These products are primarily intended for health purposes in swimming pools. In my opinion, if they are deficient in an active ingredient, they cannot perform up to the label expectations of the user, and by the same token an overformulation may create the possibility of injury to the eye or mucous membrane of an innocent user.

In either of these conditions, the instructions on the label might be considered of little use.

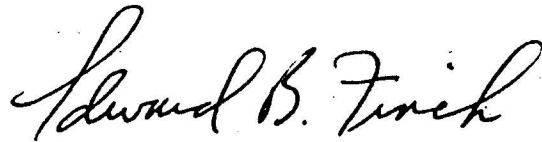
I have taken into account all of the factors that are required to be considered in determining the appropriateness of the penalty. I am of the view that the proposed penalty of \$10,200.00 is appropriate. Complainant has, in fact, not assessed a proposed penalty on the lesser violations which would have resulted in a higher proposed penalty. It has proposed a penalty only on the more serious violations.

The proposed Findings of Fact and Conclusions submitted by the parties have been considered. To the extent that they are consistent with Findings of Fact, and Discussion and Conclusions herein, they are granted, otherwise they are denied.

Having considered the entire record and based on the Findings of Fact, and Discussion and Conclusions herein, it is proposed that the following order be issued.

Final Order

Pursuant to Sec. 14(a)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136 1(a)(1)), a civil penalty of \$10,200.00 is assessed against Respondent, Alden-Leeds, Inc. for the violation which has been established on the basis of the Complaint issued on November 28, 1975.




Edward B. Finch
Administrative Law Judge

October 21, 1976

Unless appeal is taken by the filing of exceptions pursuant to Sec. 168.51 of the Rules of Practice or the Regional Administrator elects to review this decision on his own motion, the order shall become the final order of the Regional Administrator. (See Sec. 168.46(c).)

CERTIFICATE OF SERVICE

I hereby certify that two copies of this Initial Decision were mailed, regular mail, to the Hearing Clerk, USEPA, Washington, DC; one copy each was mailed, regular mail, to Jerry Kaplan, Alden-Leeds, Inc., So. Kearny, NJ, and to John Seitz, Pesticides Enforcement Division, USEPA, Washington, DC. I further certify that one copy each was hand delivered to Gerald M. Hansler, Regional Administrator, to Susan Levine, attorney for the complainant, and to the Environmental Programs Division.



Helen Lee
Regional Hearing Clerk

November 1, 1976

ALDEN LEEDS, INC.

Manufacturers of

nu-clo (10) TABLETS

"Chemicals that care for your pool"

55 JACOBUS AVENUE • SOUTH KEARNY, N. J. 07032

phone (201) 589-3544

November 15, 1976

Ms. Helen Lee
Regional Hearing Clerk
E.P.A. Region II
26 Federal Place
New York, New York 10007

Subject: Alden Leeds, Inc., I.F. & R. Docket Nos. II-110C & II-111C.
Appeal of Initial Decision.

Dear Ms. Lee:

There are a few exceptions which I have noted in the initial decision of Administrative Law Judge Edward B. Finch, which I feel must be clarified.

A. With respect to page 11, second paragraph, of the decision, Judge Finch assumes that the deficiency admitted in the Granular Chlorine was due to a quality control problem of Alden Leeds. While we must take full responsibility for each and every product which we market, in this particular case, we relied upon the original manufacturer's guarantee of product integrity. I had previously testified (TR. p.55, line 6 through p.56, line 9) that we only repacked this material from the drums of the original manufacturer.

B. With respect to page 12, first paragraph, of the initial decision, the assumption is made that Alden Leeds, Inc. does not maintain any quality control procedures. I had indicated that better quality control procedures would have to be instituted, not that there was no quality control.

C. With respect to page 13, first paragraph, "... Respondent only recently changed the labels to conform..." is in error and was answered in my initial brief dated September 17, 1976, page 2, third paragraph. As I stated in that letter, as soon as we realized the labels were not in compliance with the latest requests, this information was brought to the attention of our print shop to institute an immediate correction. As previously indicated, we were informed on the date of sampling, November 14, 1974, of needed corrections. A period of twenty-one months had elapsed since sampling, certainly sufficient time to allow us to produce new labeling at the hearing.

nu-clo the convenient modern way to perfect pool care

A COMPLETE LINE OF SWIMMING POOL CHEMICALS AND PELLETIZED CONCENTRATES

D. With respect to page 13, second paragraph, concerning my letter of December 3, 1971 (EPAX 11) and my testimony concerning that letter, further explanation is necessary to completely understand my statements. Unfortunately, I used a poor choice of words, and due to nervousness and/or tension, failed to elaborate at the hearing precisely what I meant by these statements. The statement without explanation, definitely, cast an unfavorable light upon our company.

Specifically the statements as quoted from the initial decision, "...this change was started as my letter went out, the change was already being instituted because we did not anticipate any problems with E.P.A.; on that, and it may have been printed already...that was in the works prior to approval by E.P.A....", require further explanation. Therefore, to establish the facts and show that we did not act in a lawless manner or in lack of good faith, I will detail precisely what was meant by these statements, and note how a label is updated.

1. My letter (EPAX 11) requested the addition of a certain precautionary panel to exactly nine separate registrations. Among them were Nu Clo Stabilized Chlorine Tablets, E.P.A. Reg. No. 7124-1 and Leeds All Granular Cyanuric Chlorine, E.P.A. Reg. No. 7124-6, two products sighted in these complaints. Of these nine registrations, there were a total of forty (40) different labels to be re-printed because each product or registration was available in a number of different sized containers.

2. The process of making a change to any one label must follow this sequence of events.

a. After the text is written it must be typeset in the type size and style so that it conforms to the label to which it is intended.

b. The typeset copy is then reproduced either mechanically or photographically as many times as necessary.

c. The reproduced copy is then fit into a mechanical of the label. A mechanical is a hard board exact copy of the label showing complete text and color separation. A separate mechanical or overlay is required for each individual label.

d. After the mechanical is ready, it is photographed to obtain a negative. The negative is examined, and opaqued to eliminate imperfections on the negative which would appear on a finished label.

e. The next step is masking the negative to ready it for plate making.

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f. A metal plate is then burned with intense light exposed through the masked negative, and then developed much like a photograph.

g. The plate is examined for imperfections and if acceptable it is finally ready to be run on a printing press.

3. As you can see, many steps have to be taken in order to reproduce new labeling. When I stated these changes were "...in the works prior to E.P.A. approval...that changes were being instituted..." did not mean that actual printing had already been done. The simple act of passing the text of the change to the print shop would constitute being "in the works" or being "instituted".

The passage of the text did occur as soon as my letter went out, and the long involved process was undertaken to add to each and every label the new passage. All the necessary steps had started prior to E.P.A. approval, however, at this time no orders to print labels had been issued.

While I had testified that we had our own print shop and that these labels were printed under our control, in December 1971, we did not possess the capacity to set our own type nor did we do any of our own photography work. Consequently, the time lapse for these procedures extended for a number of weeks. The text was sent out for typesetting and reproduction. Upon the return, the mechanicals were prepared, and then they were sent out for photography. The next step could not be undertaken until we received the negatives.

4. The first indications of acceptance of the proposed precautionary panel arrived in the form of a letter from E.P.A. dated January 27, 1972 (ALX 10, copy enclosed) which indicated complete approval as is. Upon receipt, the print shop was advised that we had a go ahead to print on three registrations.

It is at this time, that the chain of events become confused and unclear. Perhaps the information received by the print shop was interpreted as a go ahead on all the labels. One fact is certain, there was no possibility that the labels were printed prior to January 27, 1972. The authorization to print was issued after that date. Further, the sheer volume of the steps necessary to print could not have been accomplished in such a short time.

We know that all the labels were updated to include the requested panel. It is possible, in my opinion, that the misinterpretation of our print authorization caused the print shop to assume further E.P.A. correspondances of February 22, 1972, and March 24, 1972 did not effect the addition of the special panel.

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5. It must be pointed out that, Alden Leeds, Inc., voluntarily requested the changes, knowing that E.P.A. would review each and every registration. It should also be understood that with the enormous volume of labels the E.P.A. must process, an E.P.A. instituted review of its own accord would most likely not have occurred at that time, thereby making the existing labels still within the accepted standard.

E. With respect to page 12, fourth paragraph, Judge Finch stated that we failed to comply with E.P.A. requests of March 24, 1971, as noted in the letter of February 22, 1972. This statement is incorrect and may be substantiated by the enclosed photocopies of all E.P.A. correspondence and my answers to those correspondences. From these correspondences we clearly have satisfied all requirements requested by E.P.A., and that we were in contact with E.P.A. concerning the March 1971 requirements. I have marked each copy in the following manner:

- ALX 1 - E.P.A. letter of March 24, 1971
- ALX 2 - Alden Leeds letter of March 29, 1971
- ALX 3 - E.P.A. letter of September 20, 1971
- ALX 4 - E.P.A. letter of February 22, 1972
- ALX 5 - E.P.A. letter of October 18, 1972
- ALX 6 - Alden Leeds letter of October 24, 1972
- ALX 7 - E.P.A. letter of November 22, 1972
- ALX 8 - Alden Leeds letter of December 6, 1972
- ALX 9 - E.P.A. letter of January 11, 1973

In summation, the intention of Alden Leeds, Inc. to proceed in our orderly and legal manner has been shown in all of the previous paragraphs. We did not act in a reckless manner with complete disregard of the law. We had only the safety of the public in mind when we requested the changes of December 3, 1971. This position falls clearly in line with the purpose and intent of FIFRA. As previously indicated, better quality control has been established to insure product quality. Nothing can destroy a company faster, than a reputation of inferior, non performing products.

Accordingly, we respectfully request that this appeal be upheld after careful consideration of the explanations of fact herein stated, and that a final decision be rendered substantially reducing the civil penalty imposed. We also, respectfully, request an oral argument before the regional administrator, in the event that there are additional questions or issues which must be answered.

Thank you for your time and cooperation.

Very truly yours,
ALDEN LEEDS, INC.


Jerry Kaplan

JK/jn

Ms. Helen Lee
November 15, 1976
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c.c. E.P.A. Regional Administrator, Region II
Administrative Law Judge Edward B. Finch
Miss Susan Levine, Esq., E.P.A. Region II

ALX # 10

27 JAN 1972

ENVIRONMENTAL PROTECTION AGENCY
PESTICIDES OFFICE
WASHINGTON, D.C. 20250

Alden Leeds, Inc.
Attention: Jerry Kaplan
331 Main Street
Belleville, New Jersey 07109

Gentlemen:

Subject : NU-CLO SHQCK
EPA Reg. No. 7124-15
NU-CLO STABILIZED SLOW DISSOLVING
CHLORINE TABLETS
EPA Reg. No. 7124-12
NUCLO QUICK KILL ALGAE DESTROYER
EPA Reg. No. 7124-24
Your letter of December 3, 1971

We have examined the proposed additional precautionary labeling for these products. We have no objection to this statement. Revised labels for each product should be submitted.

Sincerely,

T E Adamczyk Rfm
T. E. Adamczyk
Chief
Fungicide-Herbicide Branch

ALX*1

ENVIRONMENTAL PROTECTION AGENCY
PESTICIDES REGULATION DIVISION
WASHINGTON, D. C. 20250

Alden Leeds, Inc.
Attention: Mr. Jerry Kaplan
331 Main Street
Belleville, New Jersey 07109

SEP 24 1971

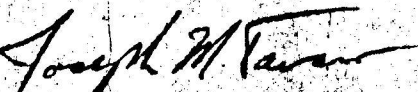
Gentlemen:

Subject : LEEDS-ALL GRANULAR CYANURIC CHLORINE
USDA Reg. No. 7124-6
Your letter of August 29, 1970

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, is being accepted at this time; and a stamped copy is enclosed for your records. However, it is subject to the comment(s) listed below. The correction(s) should be made when new labeling is printed.

1. Efficacy requirements have been revised by the Division. Submit data as indicated by the items checked on the "Efficacy Data Requirements" enclosure. The data must be developed in the presence of the "Leeds All Pool" conditioner.
2. Labels for the "Leed All" pool conditioner must be submitted for our review with regard to the subject product.
3. The front panel precautionary labeling must meet the type size and prominence requirements.

Sincerely,



Joseph M. Tavano
Head,
Registration Review (Disinfectants)

3 Enclosures

ALX#2

March 29, 1971

Mr. Joseph M. Tavano
Environmental Protection Agency
Pesticides Regulation Division
Washington, D.C. 20250

Re: Your letter of March 24, 1971
Leeds-All Granular
Cyanuric Chlorine 7124-6

Dear Mr. Tavano:

We recently developed information utilizing the two tests requested for a products we manufacture. This product is "Wonder-Tab" covered under U.S.D.A. Reg. No. 7124-6, and is the identical formulation as "Leeds-All". The difference being one is tabletized and the other is granular. Enclosed are copies of both the Wonder-Tab label and test results.

Leeds-All conditioner labeling has not been printed, however, Nu-Clo conditioner is the identical product. This conditioner is 100% cyanuric acid. We submit for your inspection copies of this label.

We would appreciate your acceptance of these test results in lieu of separate testing for the referenced product. Much lost time, money and duplication of work will then be avoided. Your prompt attention will be appreciated.

Very truly yours,

ALDEN LEEDS, INC.

J. Kaplan

ALX #3

ENVIRONMENTAL PROTECTION AGENCY
PESTICIDES OFFICE
WASHINGTON, D.C. 20250

20 SEP 1971

Alden Leeds, Inc.
331 Main Street
Belleville, New Jersey 07109

Gentlemen:

Subject : LEEDS-ALL GRANULAR CYANURIC CHLORINE
EPA Reg. No. 7124-6
Your letter of March 29, 1971

No additional data will be required for "Leeds-All" EPA Reg. No.
7124-6, pending acceptance of the test results submitted for
"Wonder-Tab", EPA Reg. No. 7124-7.

Sincerely,

Joseph M. Tavano
Joseph M. Tavano
Head Registration
Review (Disinfectants)

FEB 22 1972

ENVIRONMENTAL PROTECTION AGENCY
PESTICIDES OFFICE
WASHINGTON, D.C. 20250

Pesticides Regulation Division

Alden Leeds, Inc.
331 Main Street
Belleville, New Jersey 07109

Gentlemen:

Subject : LEEDS-ALL GRANULAR CYANURIC CHLORINE
EPA Reg. No. 7124-6
Letter of December 3, 1971 and
Re-review of Labels submitted
August 29, 1970

We have no objection to the suggested precautionary statement of your letter of December 3, 1971; however, recently obtained irritation studies (eye and skin) on similar formulations indicate that if this type of product comes in contact with the eye mucosa it may cause damage. These studies also indicate that this type of product will cause severe irritation on abraded skin, and burns on broken skin. Therefore the following precautionary statements should be added to your present labeling:

"May cause eye damage and will cause burns on broken skin.
Wash thoroughly after handling."

In addition, you should delete the signal word "Caution" on the side panel. Select another word such as: "Note", "Read", "Important," "Precaution."

A re-review of your labels submitted August 29, 1970 and accepted January 25, 1971, indicates that the requirements of our letter of March 24, 1971 have not been met. These requirements must be met to support continued registration of this product. In order to clarify these requirements, the following comments are given:

1. If concentration - between 1.0 - 1.5 p.p.m. residual chlorine are recommended in the presence of the "Leeds All" pool conditioner no efficacy data will be required, but dosages given on the label would have to be revised accordingly. If you wish to recommend concentrations of residual chlorine less than 1.0 ppm, data should be derived for this product in the presence of the "Leeds All" pool conditioner, as requested in our letter of March 24, 1971.

2

2. Since the "Leeds All" pool conditioner is intended for use in conjunction with your product, Granular Cyanuric Chlorine." labeling for the conditioner is considered as collateral labeling and must be submitted for inclusion in your product file.
3. With respect to the front panel precautionary labeling type size and prominence requirements, refer to the precautionary labeling enclosures.

Five copies of revised labeling must be submitted for our review. Draft labeling may be used for this purposed.

Sincerely,

Joseph M. Tavano/eeb

Joseph M. Tavano
Head
Disinfectant Control
Section

Enclosure

ALX #5

ENVIRONMENTAL PROTECTION AGENCY
PESTICIDES OFFICE
WASHINGTON, D.C. 20250

Pesticides Regulation Division

OCT 18 1972

CERTIFIED MAIL

In Reply Refer to
9-RR PC

Alden Leeds, Inc.
331 Main Street
Belleville, New Jersey 07109

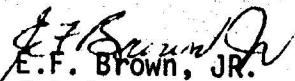
Gentlemen:

Subject : LEEDS-ALL GRANULAR CYANURIC CHLORINE
EPA Reg. No. 7124-6

A review of the record on the subject product shows that we have not received the "labeling for the "Leeds All" Pool Conditioner" requested in our letter of "February 22, 1972."

This is to notify you that in accordance with Section 4.c. of the Federal Insecticide, Fungicide, and Rodenticide Act, the registration for this product is cancelled, effective 30 days after receipt of this letter unless the requested "collateral labeling", is submitted within the specified period of other procedures are invoked under Section 4.c. of the Act.

Sincerely,


E.F. Brown, JR.
Chief
Disinfectant Branch

ALX #6

October 24, 1972

E.F. Brown, Jr.
Pesticides Regulation Division
Environmental Protection Agency
Pesticides Office
Washington, D.C. 20250

Re: Leeds All Granular Cyanuric Chlorine
Your letter of 10/18/72.

Dear Mr. Brown:

Enclosed are five draft copies of Leeds All Pool Water Conditioner to be included in our file. This product has never been marketed commercially. NuClo Pool Water Conditioner has been sold in its place.

Very truly yours,

ALDEN LEEDS, INC.

Jerry Kaplan

ALX # 7

NOV 22 1972

ENVIRONMENTAL PROTECTION AGENCY

PESTICIDES OFFICE

WASHINGTON, D.C. 20250

Pesticides Regulation Division

ALDEN LEEDS., INC.
ATTN: Mr. Jerry Kaplan
331 Main Street
Belleville., New Jersey 07109

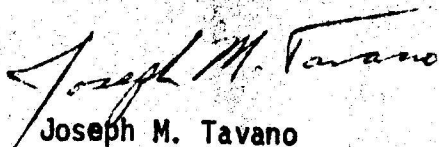
Gentlemen:

Subject: Draft collateral labeling for
LEEDS-ALL GRANULAR CYANURIC CHLORINE
E. P. A. Reg. No. 7124-6
Your letter of October 24, 1972

This is to acknowledge receipt of the collateral labeling submitted with your letter of October 24, 1972 in support of continued registration of subject product.

The submitted labeling fulfill the requirement indicated in our letters of October 18, 1972 and February 22, 1972. However, if as you have indicated in your letter the product "Leeds All Pool water conditioner" has never been marketed commercially we cannot see how you can recommend the use of a product that is not available to the consumer. Unless it is your intent to market the product, all recommendations for use of the product "Leeds All Pool Water conditioner" must be deleted from the labeling of "Leeds All Granular Cyanuric Chlorine." If the product "Nuclo Pool Water Conditioner" is to be used with the registered product submit the labeling for review and inclusion in the product file.

Sincerely,


Joseph M. Tavano
Head
Disinfectants Control
Section

ALX#8

December 6, 1972

Mr. Joseph M. Tavano
Environmental Protection Agency
Pesticides Office
Washington, D.C. 20250

Re: Leeds-All Granular Cyanuric Chlorine
C.P.A. Reg. No. 7124-6
Your letter of November 22, 1972

Dear Mr. Tavano:

Enclosed are labels for NuClo Pool Water Conditioner to be included in the product file. We intend to make available Leeds-All Pool Water Conditioner this coming season.

Thank you for your cooperation and assistance in this matter.

Very truly yours,

ALDEN LEEDS, INC.

Jerry Kaplan

ALX#9

JAN 11 1973

ENVIRONMENTAL PROTECTION AGENCY

PESTICIDES OFFICE

WASHINGTON, D.C. 20250

Pesticides Regulation Division

ALDEN LEEDS, INC.
Attention: Mr. Jerry Kaplan
331 Main Street
Belleville, New Jersey 07109

Gentlemen:

Subject: LEEDS-ALL GRANULAR CYANURIC CHLORINE
EPA Reg. No. 7124-6
Your letter of December 6, 1972

This is to acknowledge receipt of the collateral labeling submitted with your letter of December 6, 1972. We note your statement that "Leeds All Pool Water Conditioner" will be made available to consumers.

Sincerely,

Joseph M. Tavano /092

Joseph M. Tavano
Head
Disinfectant Control
Section